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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,541	05/10/2001	Jonathan S. Stinson	PC10247C	7185

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	14

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,541	STINSON, JONATHAN S.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 68-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 68-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 33-46 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 56-88 must be renumbered 68-100 (claims will be referred to as 68-100 within this office action). Please note that when renumbering, to also renumber the dependencies.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 68-79, 86, and 90-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "the extremity" in line 6. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the extremity" to --an extremity--. Claims 68-79 depend upon claim 33 and inherit all problems associated with the claim.

Claim 74 recites the limitation "the proximal direction" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the proximal direction" to --a proximal direction--.

Claim 86 recites the limitation "the proximal direction" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the proximal direction" to --a proximal direction--.

Claim 92 recites the limitation "the proximal direction" in line 8. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the proximal direction" to --a proximal direction--. Claim 92 also recites, "the occlusion device may pass through the distal opening of the deployed occlusion device", and it is unclear how the occlusion device passes through the occlusion device. It is assumed applicant mistakenly claimed the occlusion device instead of the distal tip, if this is true, a correction should be made. Claims 93-100 depend upon claim 92 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33 and 68-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Ryan (USPN 5,830,217, cited in previous office action). Referring to claims 33, 73, 74, 80, 86, and

92, Ryan discloses an occlusion device delivery system comprising a tubular body (3, 2) including a distal portion (seen in figures), a releasably deployable occlusion device (1) positioned on the distal portion of the tubular body (3), and a distal tip (12, 15, 16) disposed on distal portion of the tubular body (3) to form an extremity of the tubular body (Ryan discloses a distal end of the catheter to be 5, shown in fig.1, and the material 12, 15, and 16, is shown to cover the distal end 5, therefore 12, 15, and 16 may *be* the distal tip and therefore, the extremity of the tubular device, since it is located at the distal end; 12, 15, and 16 are located at the extremity of the tubular catheter 3, therefore, help *form* the extremity; also, applicant has argued that Ryan discloses the catheter extending distally from the tip, therefore, does not form the extremity. The examiner disagrees. Ryan discloses only the *guidewire* to extend distally from the tip 12, 15, 16, and the catheter 13 only extends *proximally*, therefore the tip 12, 15, 16 *does form the extremity* of the tubular catheter body 3; see col.4, lines 41-45; also, Ryan's method of production of the dissolvable tip is to dip the balloon catheter into a composition, therefore, in order to dip the catheter, an entire end, the distal tip, will inherently be coated with the dissolvable composition), the distal tip (12, 15, 16) including at least a partially bioabsorbable or dissolvable material (col.4, lines 47-59), wherein the distal tip (12, 15, 16) is configured to remain disposed on the tubular body during the entire bioabsorption or dissolution process (it dissolves in a matter of minutes, and therefore, will remain on the catheter until done dissolving; col.3, lines 9-14; col.4, lines 54-59 and does not necessarily entirely dissolve, and therefore, will definitely remain on the catheter, col.6, lines 17-22), and whereby the tip (12, 15, 16) is configured to pass proximally through a distal opening in a deployed occlusion device (1) when the tubular body (3) is displaced in a proximal direction (since Ryan disclosed deployment

before entire dissolution, the tip, before entirely dissolved may be pulled proximally, col.6, 17-22, col.5, lines 58-62, col.8, lines 18-27, especially in the configuration in fig.4, wherein the composition of the tip 16 is underneath the tip).

Referring to claims 68, 81, and 93, Ryan discloses the tip (12, 15, 16) having a guidewire lumen (perforation in distal end of capsule, col.4, lines 42-44).

Referring to claims 69, 82, and 94, Ryan discloses a solid tip (col.6, lines 17-19, 65-67).

Referring to claims 70-72, 83-85, and 95-96, Ryan discloses a tip (12, 15, 16) configured to bioabsorb or dissolve to a smaller profile in less than 15 min, preferably 5-10 min (any rate, col.6, lines 29-31, 51-53; col.7, lines 43-63).

Referring to claims 75 and 87, Ryan discloses a tip configured to bioabsorb or dissolve substantially away (col.3, lines 9-12).

Referring to claims 76, 88, and 97, Ryan discloses the tip (12, 15, 16) having a smooth transition at an edge of the tubular body (3), see figures 2-5.

Referring to claims 77-79, 89-91, and 98-100, Ryan discloses the occlusion device (1) to be a self-expanding stent (col.3, lines 54-67) and the tubular body (3) to be a catheter (col.3, lines 40-41).

Claims 33, 68, 69, 72-82, 85-94, and 97-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (USPN 5,603,698, cited in previous office action). Referring to claims 33, 72, 73, 74, 80, 85, 86, and 92, Roberts discloses an occlusion device delivery system (2) comprising a tubular body (4) including a distal portion (10), a releasably deployable occlusion device (14) positioned on the distal portion of the tubular body (4), and a distal tip (26)

disposed on the distal portion (10) of the tubular body (4) to form an extremity of the tubular body (fig.1, 2f, since Roberts tip 26 is slidable on the body 4, it may be located anywhere along the catheter 4, including the extremity, and indeed is located at an extremity, at some point during implantation, somewhere between fig.1 and fig.2f), the distal tip (26) including at least a partially bioabsorbable or dissolvable material (col.6, lines 30-42), wherein the distal tip is *configured* to remain disposed on the tubular body during the entire bioabsorption or dissolution process (even though Roberts discloses release of the tip from the catheter, the tip does initially sit on the catheter, and is configured to remain disposed on the catheter, that is it has all the claimed structural parts in this product claim to perform the function called for; also, Roberts discloses the tip to be *selectively dislodgeable*, implying the tip is capable of remaining on the catheter, col.1, lines 58-61), and whereby the tip (26) is *configured* to bioabsorb or dissolve to a smaller profile (will bioabsorb or dissolve eventually, col.6, lines 30-42 and at that time, will *be capable* due to its configuration, of passing proximally) and pass proximally through a distal opening in a deployed occlusion device (14) when the tubular body (4) is displaced in a proximal direction.

Referring to claims 68, 81, and 93, Roberts discloses the tip (26) having a guidewire lumen (35).

Referring to claims 69, 82, and 94, Roberts discloses a solid tip (fig.1).

Referring to claims 75 and 87, Roberts discloses a tip (26) configured to bioabsorb or dissolve substantially away (fig.2f-2h; col.6, lines 30-43).

Referring to claims 76, 88, and 97, Roberts discloses the tip (26) having a smooth transition (28, 29) at an edge of the tubular body (4).

Referring to claims 77-79, 89-91, and 98-100, Roberts discloses the occlusion device (14) to be a self-expanding stent (col.4, lines 20-24) and the tubular body (4) to be a catheter (col.3, lines 65-67).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER